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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/820,262	FINKEL ET AL.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 14, 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges Applicants' reply filed June 14, 2007, which amends claims 1-8 and adds new claim 16.

Claims 1-16 are pending and under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, step c), the phrase "said lipid" lack antecedent basis.

In claim 6, the identity of one or more objects referenced by most of the recited abbreviations lacks antecedent basis in claim 6 and antecedent support in the specification. In addition, the identity of one or more objects referenced by "major histocompatibility complex (MHC)" is not clear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 7, 8, 10 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Samuelson *et al.* (US 5,260,004).

Samuelson *et al.* describe a method for producing a fluid planar lipid bilayer-based membrane-anchored ligand system comprising:

a. providing a solid surface (see *e.g.*, col. 4, line 24, "biosensor") in contact with a lipid bilayer (see col. 4, line 23, "processed into desired multilayers") containing lipids conjugated to a first specific binding pair member (see Abstract, second sentence, "biotinylated lipids");

b. linking (see *e.g.*, Abstract, third sentence, "[c]onjugated") a ligand (see Abstract, third sentence, "proteinaceous component") to a second specific binding pair member,

> the second specific binding pair member having binding affinity for said first specific binding pair member (see Abstract, third sentence, "a biotin-binding component made up of an avidin or streptavidin"); and

c. contacting the lipid bilayer of step a) with the linked ligand of step b) (see *e.g.*, Abstract, last sentence, "build up a multilayered complex"),

whereby contact of the lipid bilayer with said second binding pair member linked to said ligand results in anchoring (see *e.g.*, Abstract, last sentence, "build up") of the ligand to said lipid, thereby forming a fluid planar lipid bilayer-based membrane-anchored ligand system.

Claims 1, 2, 5, 7, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Penner *et al.* (US 4,830,952).

Penner *et al.* describe a method for producing a fluid planar lipid bilayer-based membrane-anchored ligand system comprising:

a. providing a solid surface in contact with a lipid bilayer (see col. 4, lines ~37-38, noting the layer closest to the "substrate") containing lipids conjugated to a first specific binding pair member (see *e.g.*, col. 6, Formulae VI and VII);

b. linking a ligand (see col. 5, lines 47-48, "Z represents one or more charge balancing counter ions"; lines 66-68, "Z can be a substituent of R^1, R^2, or R^{3}"; see also, col. 2, lines 58-60, "moieties which can be photoactivated to undergo a crosslinking reaction") to a second specific binding pair member (see *e.g.*, col. 5, Formulae III, IV, and V),

the second specific binding pair member having binding affinity (see col. 4, line 26, "more stable") for said first specific binding pair member (see col. 4, lines ~32-36, noting the proximity of "L" groups between the top layer and the middle layer); and

c. contacting (see col. 14, line 29, "moving the support through a liquid interface") the lipid bilayer of step a) with the linked ligand of step b),

whereby contact of the lipid bilayer with said second binding pair member linked to said ligand results in anchoring of the ligand to said lipid (see col. 4, lines ~32-36, noting the proximity of "L" groups between the top layer and the middle layer), thereby forming a fluid planar lipid bilayer-based membrane-anchored ligand system.

Claims 1-3, 5-11 and 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Boxer *et al.* (US 6,228,326).

Boxer *et al.* describe a method for producing a fluid planar lipid bilayer-based membrane-anchored ligand system comprising:

a. providing a solid surface in contact with a lipid bilayer (see Fig. 1) containing lipids conjugated to a first specific binding pair member (see *e.g.*, col. 13, lines 47-49, "The bilayer is formed of or derivatized with metal-chelating moieties"; see *also*, line 56, "biotinylated lipids");

b. linking a ligand to a second specific binding pair member (see *e.g.*, col. 13, line 50, "expressed His-tagged protein"; see *also*, lines 57-58, "a biomolecule linked or coupled to avidin or streptavidin"),

the second specific binding pair member having binding affinity for said first specific binding pair member (see *e.g.*, col. 13, lines 53-55, "Specific high-affinity molecular

interactions may also be employed to link selected biomolecules to a supported bilayer"); and

c. contacting the lipid bilayer of step a) with the linked ligand of step b) (see *e.g.*, col. 13, lines 36-37, "linking biomolecules such as proteins to a supported lipid bilayer"),

whereby contact of the lipid bilayer with said second binding pair member linked to said ligand results in anchoring of the ligand to said lipid (see *e.g.*, col. 13, lines 53-55, "Specific high-affinity molecular interactions may also be employed to link selected biomolecules to a supported bilayer"), thereby forming a fluid planar lipid bilayer-based membrane-anchored ligand system.

With respect to newly added claim 16, Boxer *et al.* describe a dextran kooshion (see col. 3, line 45).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 4, 6, 11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samuelson *et al.* (US 5,260,004) in view of Ladner *et al.* (US 5,223,409).

Samuelson *et al.* describe a method for producing a lipid-ligand system as substantially described *supra*.

Samuelson *et al.* do not describe a method incorporating a "cell" or "virus".

However, Ladner *et al.* describe optimization of affinity separation technology (see col. 83, lines 25+) incorporating a "cell" or "virus" (see Abstract).

It would have been obvious to a person of ordinary skill to optimize the lipid-ligand system of Samuelson *et al.* by incorporating a "cell" or "virus" because Ladner *et al.* discovered that such optimization provides "a novel binding domain having a desired affinity" (see Abstract, fifth sentence).

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samuelson *et al.* (US 5,260,004) in view of Sivars *et al.*, 743 J. CHROMATOGR. B 307 (2000).

Samuelson *et al.* describe a method for producing a lipid-ligand system as substantially described *supra*.

Samuelson *et al.* do not describe a method incorporating "nickel-histidine" binding pairs.

However, Sivars *et al.* describe optimization of affinity separation (see Title, "Affinity partitioning") incorporating poly(histidine)-metal binding pairs (see Title; *see also*, p. 312, left column, first full paragraph, "the general binding strength of chelated metal ions towards histidines decreases in the order: $Cu^{2+} > Ni^{2+} > Zn^{2+} > Co^{2+}$").

It would have been obvious to a person of ordinary skill to optimize the lipid-ligand system of Samuelson *et al.* by incorporating poly(histidine)-metal binding pairs because Sivars *et al.* discovered that such optimization provides "a fast and mild affinity procedure for the purification of integral membrane proteins" (see Abstract, last sentence).

Response to Arguments

In prior Office Action, claims 1, 2, 5, 7, 8, 10 and 14 were rejected under 35 U.S.C. 102(b) as being anticipated by Samuelson *et al.* (US 5,260,004). Claims 1, 2, 5, 7, 13 and 14 were rejected under 35 U.S.C. 102(b) as being anticipated by Penner *et al.* (US 4,830,952). Claims 3, 4, 6, 11 and 15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Samuelson *et al.* (US 5,260,004) in view of Ladner *et al.* (US 5,223,409). And, claims 9 and 10 were rejected under 35 U.S.C. 103(a) as being unpatentable over Samuelson *et al.* (US 5,260,004) in view of Sivars *et al.*, 743 J. CHROMATOGR. B 307 (2000).

In response, Applicants amend independent claim 1 to now recite a method of making a "lipid bilayer" system. Applicants argue that none of the cited prior art teach such a "lipid bilayer", but rather, teach devices limited to monolayers or multilayers. In addition, Applicant appear to argue that neither the prior Office Action nor Penner *et al.* teach a step of "anchoring" a ligand because neither the prior Office Action nor Penner *et al.* provide an electrostatic/kinetic rationale for the cartoon "anchoring" depicted in the middle of column 4.

Applicants' arguments have been carefully considered but are not persuasive.

Examiner observes that step c) of claim 1 merely requires "anchoring" a ligand to a lipid. Claim 1 is anticipated because both Samuelson *et al.* and Penner *et al.* clearly and unambiguously describe methods of making multilayer films (*i.e.*, films possessing at least one bilayer) where a ligand is "anchored" to a lipid. For example, Samuelson *et al.* describe a "build up" of lipid layers into multilayers (see *e.g.*, Abstract, last sentence, "build up"). Similarly, Penner *et al.* describe stable stacking of lipid layers into multilayers (see col. 4, lines ~32-36, noting the proximity of "L" groups between the top layer and the middle layer).

Although neither the prior Office Action nor Penner *et al.* provide an electrostatic/kinetic rationale for the cartoon "anchoring" depicted in the middle of column 4, Examiner posits that skilled artisans, as evidence by Blodgett, 57 J. AM. CHEM. SOC. 1007 (1935), are able to perform similar head-to-head lipid "anchoring" and do not require an electrostatic/kinetic rationale.

Conclusion

No claims are allowable at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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djv

/Mark L. Shibuya/
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